K010006
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JUL 2 5 2001

510(k) SUMMARY

510(k) NUMBER:	PENDING
SUBMITTED BY:	Applied Medical Resources Corporation 22872 Avenida Empresa Rancho Santa Margarita, CA-92688 (949) 713-8000
CONTACT PERSON:	Anil Bhalani Director of Regulatory Affairs and Clinical Programs
DATE OF PREPARATION:	May 24, 2001
NAME OF DEVICE:	Applied Drainage Catheter
CLASSIFICATION NAME:	Urological Catheter [21 CFR 876.5130 (a)]
TRADE NAME:	Applied Drainage Catheter
PREDICATE DEVICE:	Bardex Foley Catheter, C.R. Bard, Inc, Covington, GA.

INTENDED USE STATEMENT:

The Applied Drainage Catheter is designed for use in the drainage and/or collection and/or measurement of urine. Drainage is accomplished by inserting the catheter through the urethra and into the bladder.

SUMMARY STATEMENT:

The Applied Drainage Catheter is constructed from materials that are commonly used in medical devices in similar applications. The single 8Fr thru-lumen lumen catheter body of a 12Fr outer diameter is extruded from C-Flex®. The catheter's hub, balloon and suture are made of polyester.

The Applied Drainage Catheter is placed inside the body for drainage of urine from the bladder by gently pushing it up the urethra. As the catheter is pushed up the urethra, the mesh bulb stretches and folds/compresses over the catheter body into a low profile shape. As soon as the bulb is inside the bladder it expands to its bulb shape. Once placed in position if the catheter is pulled the bulb forms a disc like shape which resists removal of the catheter much like the liquid filled balloon of a traditional Foley Catheter.

For removal, the catheter body is cut above the hub. This releases the suture and thereby frees the bulb to be pushed past the tip of the catheter allowing it to stretch into a low profile or a smaller diameter tubular shape for easy removal through the urethra.

ODE/FDA
APPLIED DRAINAGE CATHETER
Applied Medical, May 2001

The Applied Drainage Catheter is similar to Foley Catheters currently marketed in function and performance. Performance and functional testing standards are based on the FDA guidance, *Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters and* ASTM Standard, *ASTM F 623-89*. The following tests were performed on the Applied drainage Catheter.

a. Flow rate through the drainage lumen
b. Ballon/Bulb integrity
c. Balloon/Bulb deflation reliability
d. Balloon/Bulb response to pullout
e. Ballon/Bulb and shaft size
f. Cyclic loading of the mesh bulb
g. Attachment strength of the mesh bulb to the catheter body
h. Tear Strength and Elongation at Tear of the Tether

Materials used in the manufacture of the Applied Drainage Catheter were successfully tested to verify biocompatibility of the materials per ISO 10993-1.

Based on the above testing it was concluded that the Applied Drainage Catheter is substantially equivalent to predicate devices and introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2001

Mr. Anil Bhalani
Vice President, Regulatory Affairs
and Clinical Programs
Applied Medical Resources, corp.
22872 Avenida Empresa
RANCHO SANTA MARGARITA CA 92688

Re: K010006
Drainage Catheter or Foley Catheter
Dated: May 24, 2001
Received: May 29, 2001
Regulatory Class: II
21 CFR 876.5130/Procode: 78 EZL

Dear Mr. Bhalani:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the APPLIED DRAINAGE CATHETER "Indications for Use" as required.

510(k) Number: Not assigned

Device Name: DRAINAGE CATHETER

Indications for Use: The Applied Drainage Catheter is indicated for use in the drainage and/or collection and/or measurement of urine. Drainage is accomplished by inserting the catheter through the urethra and into the bladder.

Signature: _____ Title: *Director RA/Clinical Programs* Date: *5-24-01*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___√___ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

(Optional Format -2-96)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010006